

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Keropur and Keropur DP Series

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

August 2018

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1503	BASF Australia Ltd	Polymer in Keropur and Keropur DP Series	No	≤ 500 tonnes per annum	Component in fuel additives

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these

circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component in fuel additives, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDS of products containing the notified polymer were provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

BASF Australia Ltd (ABN 62 008 437 867)
Level 12
28 Freshwater Place
Southbank VIC 3006

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual impurities, and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

Polymer in Keropur and Keropur DP Series

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 g/mol.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Colourless
Melting Point/Glass Transition Temperature	-74 °C
Density	926 kg/m ³ at 20 °C
Water Solubility	0.010 – 0.076 g/L at 20 °C
Dissociation Constant	Not determined. The notified polymer has very low water solubility.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	200 – 500	200 – 500	200 – 500	200 – 500	200 – 500

Use

The notified polymer is a friction modifier for use in diesel and petrol fuels. It will be imported as a component of a fuel additive package at < 30% concentration. The fuel additive package will be reformulated in Australia by blending with diesel or petrol fuel and other additives. The final concentration of the notified polymer in the fuel will be < 1%.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 2,000 mg/kg bw	yes	OECD TG 423
2. Skin irritation		no	
a) <i>in vitro</i> EpiDerm™	non-corrosive		OECD TG 431
b) Reconstructed Human Epidermis Model	non-irritating		OECD TG 439
3. Eye irritation		no	
a) <i>in vitro</i> Bovine Corneal Opacity and Permeability test (BCOP)	non-corrosive or severe eye irritant		OECD TG 437
b) EpiOcular™ test	non-irritating		
4. Skin sensitisation		no	
a) <i>in chemico</i> Direct peptide reactivity Assay	Inconclusive		OECD TG 442C
b) <i>in vitro</i> ARE-Nrf2 Luciferase Test	No evidence of keratinocyte activation potential		OECD TG 442D
c) <i>in vitro</i> human Cell Line Activation Test	No evidence of dendritic cell induction		Similar to OECD TG 442E
5. Genotoxicity - bacterial reverse mutation assay	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

The notified polymer was of low acute oral toxicity to rats (Bioassay, 2015). Animals in both groups exhibited an impaired general state and piloerection. The onset of these signs varied between animals and groups with the earliest onset recorded at 2 hours after exposure.

Two *in vitro* skin irritation studies (BASF, 2015a) and two *in vitro* eye irritation studies (BASF, 2015b) were conducted to evaluate the irritation potential of the notified polymer. The notified chemical was non-irritating to the skin or eyes when tested at 100% concentration in the EpiDerm™ test, EpiOcular™ test or BCOP test. No significant reduction in cell viability was observed in both *in vitro* eye irritation or skin irritation tests when compared to controls. Based on the results of the *in vitro* studies, the notified chemical is not classified as a skin or eye irritant.

A battery of three tests consisting of one *in chemico* (Direct Peptide Reactivity Assay (DPRA)) and two *in vitro* (ARE-Nrf2 Luciferase and h-CLAT) cell based assays were conducted to evaluate the sensitisation potential of the notified chemical (BASF, 2015c). The tests are part of an Integrated Approach to Testing and Assessment (IATA) which address specific events on the Adverse Outcome Pathway (AOP) leading to development of skin sensitisation (OECD, 2016). The tests are thus considered relevant for assessment of the skin sensitisation potential of the notified chemical, together with other supporting information.

The notified chemical showed negative responses in two of the three tests (ARE-Nrf2 Luciferase and h-CLAT assays). The DPRA assay recorded a negative mean depletion (-2.96%) of lysine containing peptides. The mean peptide depletion was calculated to be 5.46% as under the prediction model (OECD TG 442C) negative depletions are considered as zero. Under the model, the notified polymer is considered to show no or minimal reactivity in the DPRA. However, due to the limited solubility of the test substance no firm conclusion on the lack of reactivity should be made, and the DPRA result should be considered as inconclusive.

Overall the notified chemical is not expected to be a skin sensitiser.

The notified polymer was not mutagenic in a bacterial reverse mutation assay (BASF, 2015d).

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

Occupational Health and Safety Risk Assessment

Workers may be exposed dermally to the notified chemical at < 30% concentration during reformulation processes and at < 1% concentration when using diesel fuel. Exposure is expected to be mitigated by the use of enclosed and automated processes and the use of personal protective equipment during reformulation procedures and by safe work practices for handling fuel such as transfer, dispensing and cleaning processes. Under the conditions of the occupational settings described by the notifier, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

Public Health and Safety Risk Assessment

The public may have incidental exposure to the notified polymer through operations such as refilling vehicles. Given the moderately low concentration of polymer the public will be exposed to (< 1%), and the low hazard when used in the proposed manner the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, leading to chelation of essential nutrients (Boethling RS & Nabholz VJ, 1997). However, this does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

The notified polymer will be imported as a component of a fuel additive formulation. The notified polymer will be reformulated into the finished fuel by blending with diesel and other additives. The reformulation processes are mostly enclosed and automated, and only occur at refineries or bulk fuel storage facilities. Accidental spills of the products containing the notified polymer during reformulation, transport and storage are expected to be collected for recycling or disposal in accordance with local government regulations. The notifier estimated that up to 1% of the import volume of the notified polymer could remain as residues in empty containers, which is expected to be disposed of by approved waste management facilities in accordance with local government regulations.

The notified polymer in the finished fuel will be used as a friction modifier for cleaning and keeping the engine inlet systems clean. Most of the notified polymer is expected to be combusted in engines to yield oxides of carbon and water during use. Thus, release of the notified polymer to the aquatic environment in ecologically significant concentration is not expected. The notified polymer is not expected to bioaccumulate based on its high molecular weight.

Therefore, based on its assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

BIBLIOGRAPHY

- BASF (2015a) [notified polymer] *In vitro* Skin Irritation and Corrosion Turnkey Testing Strategy (Study No. 69V0664/14A202, September, 2015). Ludwigshafen, Germany, BASF SE Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).
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- Bioassay (2015) [notified polymer] Acute Oral Toxicity Study in Rats (Study No. 15-BF-OT005, September, 2015) Ludwigshafen, Germany, Bioassay Labor für biologische Analytik GmbH
- Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.
- OECD (2017), Guidance Document on the Reporting of Defined Approaches and Individual Information Sources to be Used within Integrated Approaches to Testing and Assessment (IATA) for Skin Sensitisation, OECD Series on Testing and Assessment, No. 256, OECD Publishing, Paris, <https://doi.org/10.1787/9789264279285-en>.